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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,434	09/14/2006	Kirby Siemering, Victoria	18896	6151

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EXAMINER	
SALMON, KATHERINE D	

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,434	SIEMERING, VICTORIA ET AL.	
	Examiner	Art Unit	
	KATHERINE SALMON	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2009*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17, 20-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17, 20-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This requirement for restriction is in response to papers filed 1/12/2009.

2. Claims 1-17, 20-27 are pending. Claims 18-19 have been cancelled.

3. Based upon the new claims (# 26-27) presented in the papers filed 1/12/2009, a claim to the method of genotyping the combination of connexion 26, pendrin, mitochondrial 12s rRNA, and usherin has been added. This combination was not presented in the claim set for the restriction mailed out on 4/24/2008.

4. A phone call was made to Xiaochun Zhu on March 17, 2009 for an oral election to the restriction requirement set forth below, however the call did not result in an election being made. The newly added group is Group VI. The restriction requirement has further been amended in the "Further restriction requirement" section to allow for a combination of SEQ ID Nos to be elected.

5. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, and 20, in part, drawn to a method of genotype comprising RNA or DNA from connexion 26.

Group II, claim(s) 1-17, 20, in part, drawn to a method of genotype comprising RNA or DNA from pendrin.

Group III, claim(s) 1-17, 20, in part, drawn to a method of genotype comprising RNA or DNA from mitochondrial 12s rRNA.

Group IV, claim(s) 1-17, 20, in part, drawn to a method of genotyping comprising RNA or DNA from usherin.

Group V, claim(s) 21-25, drawn to a set of one or more oligonucleotides and a kit.

Group VI, claim(s) 1-17, 20, in part, drawn to a method of genotyping comprising RNA or DNA from conexion 26, pendrin, mitochondrial 12s rRNA, and usherin.

6. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. According to PCT Rule 13.2, unity of invention exists only when a shared same or corresponding special technical feature is a contribution over the prior art. The technical feature, which is shared by Groups I-VI, is a genotyping method to detect deafness mutations. Groups I-VI do not share a special technical feature over the art because Hone et al. (2002 Otolaryngology Clinics of North America Vol 35 p. 751) teaches a genotyping method to detect deafness mutations of connexin (abstract). Therefore, a genotyping method to detect deafness mutations fails to make a contribution over the prior art; there is no special technical feature between Groups I-VI.

FURTHER RESTRCITON REQUIREMENT

7. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

As discussed below, a restriction requirement is being made such that applicant

is required to further elect for Groups I-IV and VI **a specific SEQ ID No. or a specific combination of SEQ ID NO. from SEQ ID 1-32** and for Group V **a specific SEQ ID No. or a specific combination of SEQ ID NO. from SEQ ID 1-64.** It is noted that claims generic to SEQ ID Numbers will be examined as generic.

The claims are drawn to "at least one" from the group comprising the least of genes. Therefore each different combination of a specific gene or specific combinations of genes are separate inventive concepts.

For example, each of the following are combinations which are represented in each of the Groups presented above and each represents a different inventive concept:

A. the combination of SEQ ID No. 33

B. the combination of SEQ ID No. 35 and 36

C. the combination of SEQ ID NO. 33, 35, and 36.

These combinations of genes do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the description fails to disclose that all of the genes in each of the combinations share a common property or activity. While each combination of genes might serve to detect its own respective full length DNA, due to the lack of sequence homology between each gene, one gene cannot be used to amplify the same region of DNA as another.

In the preceding example, the region that is amplified in Combination A is distinct from the regions amplified in Combinations B and C, and vice versa. Therefore each combination of genes represents a different inventive concept

Moreover, since the polynucleotides are not homologous to each other, they fail to share a common structure, i.e., a significant structural element. The sugar-phosphate backbone cannot be considered a significant structural element, since all nucleic acid molecules share it. Therefore, the genes do not share any significant structural element and cannot be considered as having the same or corresponding technical feature.

The mere fact that genes are derived from the same source (human genome) is not sufficient to meet the criteria for unity of invention. The polynucleotides fail to share a common property or activity and fail to share a common structure. Since neither of these two requirements is met, the group of polynucleotide molecules claimed does not meet the requirement of unity of invention.

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE SALMON whose telephone number is (571)272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katherine Salmon/
Examiner, Art Unit 1634

/Juliet C Switzer/
Primary Examiner, Art Unit 1634